

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TAIHO PHARMACEUTICAL CO., LTD.  
and TAIHO ONCOLOGY, INC.,

Plaintiffs,

v.

NATCO PHARMA LTD. and NATCO  
PHARMA, INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. (collectively, “Taiho” or “Plaintiffs”), for their Complaint for Patent Infringement and Declaratory Judgment against Natco Pharma Ltd. and Natco Pharma, Inc. (collectively, “Natco” or “Defendants”) allege as follows:

**THE PARTIES**

1. Plaintiff Taiho Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-27 Kandanishiki-cho, Chiyoda-ku, Tokyo 101-8444, Japan.

2. Plaintiff Taiho Oncology, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 101 Carnegie Center, Suite 101, Princeton, New Jersey 08540.

3. Upon information and belief, defendant Natco Pharma Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Natco House, Road No. 2, Hyderabad 500034, India.

4. Upon information and belief, defendant Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 241 West Roseville Road, Lancaster, Pennsylvania 17601.

5. Upon information and belief, Natco Pharma Ltd. and Natco Pharma, Inc. are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

6. Upon information and belief, Natco Pharma, Inc. is a wholly owned subsidiary of Natco Pharma Ltd.

7. Upon information and belief, Natco Pharma Ltd. prepared and submitted Natco's Abbreviated New Drug Application ("ANDA") No. 214008 (tipiracil HCl/trifluridine oral tablets) ("Natco's ANDA Product") to the United States Food and Drug Administration ("FDA").

8. Upon information and belief, Natco Pharma Ltd. and Natco Pharma, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Natco's ANDA Product, and enter into agreements with each other that are nearer than arm's length.

9. Upon information and belief, Natco Pharma Ltd. and Natco Pharma, Inc. participated in, assisted with, and cooperated in the acts complained of herein.

10. Upon information and belief, following any FDA approval of Natco's ANDA, Defendants will act in concert to manufacture, market, distribute, and/or sell Natco's ANDA Product throughout the United States, including within Delaware.

### **NATURE OF THE ACTION**

11. This is a civil action for infringement of U.S. Patent Nos. RE46,284 E (“the ‘284 patent”), 9,527,833 C1 (“the ‘833 patent”), and 10,457,666 B2 (“the ‘666 patent”) (collectively, “the patents-in-suit”) arising under the United States Patent Laws, Title 35, United States Code § 100, *et seq.*, and in particular under § 271, as well as a civil action for declaratory judgment of patent infringement of the patents-in-suit under 28 U.S.C. §§ 2201-02. Taiho seeks declaratory relief, injunctive relief, attorneys’ fees, and any other relief the Court deems just and proper.

12. This action relates to ANDA No. 214008, which Natco filed or caused to be filed under 21 U.S.C. § 355(j) with the FDA, for approval to manufacture, use, and/or offer for sale a generic copy of Taiho’s Lonsurf® (trifluridine and tipiracil) tablets throughout the United States prior to the expiration of the patents-in-suit.

### **JURISDICTION AND VENUE**

13. This is a civil action for infringement arising under the United States Patent Laws, including 35 U.S.C. § 271, as well as a civil action for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201-02.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201-02.

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

16. This Court has personal jurisdiction over Natco Pharma Ltd. because, *inter alia*, Natco Pharma Ltd., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Natco’s ANDA Product to residents of the State of Delaware; (3) owns subsidiary companies that are organized under the laws of the State of Delaware, including Natco Pharma, Inc.; (4) maintains a broad

distribution network within the State of Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

17. Upon information and belief, Natco Pharma Ltd. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

18. Upon information and belief, Natco Pharma Ltd. has substantial, continuous, and systematic contacts with the State of Delaware including Natco Pharma Ltd.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

19. Upon information and belief, Natco Pharma Ltd., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Natco's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

20. Upon information and belief, Natco Pharma Ltd., and/or its subsidiaries, affiliates, or agents, intends to place Natco's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

21. Upon information and belief, Natco Pharma Ltd. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

22. Natco Pharma Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware in the matters, *inter alia*, of *Pfizer Inc. et al. v. Natco Pharma, Inc. et al.*, 19-cv-753 (D. Del.); *Novartis Pharm. Corp. et al. v. Natco Pharma Ltd.*, 15-cv-987 (D. Del.); and *Cephalon, Inc. v. Breckenridge Pharma., Inc. et al.*, 14-cv-671 (D. Del.).

23. Upon information and belief, Natco Pharma Ltd. participated in the preparation, development, and filing of ANDA No. 214008, and its underlying subject matter, with the intent to market, sell, and/or distribute Natco's ANDA Product to residents of the State of Delaware. Taiho's causes of action arise from Natco Pharma Ltd.'s contact with the State of Delaware.

24. Venue is proper in this Judicial District as to Natco Pharma Ltd. because, *inter alia*, Natco Pharma Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this Judicial District.

25. This Court has personal jurisdiction over Natco Pharma, Inc. because Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware. Natco Pharma, Inc. has a registered agent located at 108 West 13<sup>th</sup> Street, Wilmington, Delaware, 19801. This court also has personal jurisdiction over Natco Pharma, Inc. because, *inter alia*, Natco Pharma, Inc., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Natco's ANDA Product to residents of the State of Delaware; (3) maintains a broad distribution network within the State of Delaware; and/or (4) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

26. Upon information and belief, Natco Pharma, Inc. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State

of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

27. Upon information and belief, Natco Pharma, Inc. has substantial, continuous, and systematic contacts with the State of Delaware including Natco Pharma, Inc.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

28. Upon information and belief, Natco Pharma, Inc., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Natco's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

29. Upon information and belief, Natco Pharma, Inc., and/or its subsidiaries, affiliates, or agents, intends to place Natco's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

30. Upon information and belief, Natco Pharma, Inc. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

31. Natco Pharma, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware in the matter of *Pfizer Inc. et al. v. Natco Pharma, Inc. et al.*, 19-cv-753 (D. Del.).

32. Upon information and belief, Natco Pharma, Inc. intends to market, sell, and/or distribute Natco's ANDA Product to residents of the State of Delaware. Taiho's causes of action arise from Natco Pharma, Inc.'s contact with the State of Delaware.

33. Venue is proper in this Judicial District as to Natco Pharma, Inc. because, *inter alia*, Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this Judicial District.

**LONSURF®**

34. Plaintiff Taiho Oncology, Inc. is the holder of the New Drug Application ("NDA") No. 207981 for the manufacture and sale of trifluridine and tipiracil tablets, 15 mg and 20 mg, and sells the product in the United States under the registered trademark Lonsurf®.

35. The FDA approved NDA No. 207981 for the 15 mg and 20 mg tablets on September 22, 2015.

36. Plaintiff Taiho Oncology, Inc. sells and distributes Lonsurf® throughout the United States pursuant to NDA No. 207981.

37. Lonsurf® is indicated for the treatment of metastatic colorectal cancer that has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy as well as the treatment of metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. A copy of the February 22, 2019 Lonsurf® Label is attached as Exhibit A.

**PATENTS-IN-SUIT**

38. The ‘284 patent, entitled “Method of Administering an Anticancer Drug Containing  $\alpha,\alpha,\alpha$ -Trifluorothymidine and Thymidine Phosphorylase Inhibitor,” was duly and legally reissued by the United States Patent and Trademark Office (“USPTO”) on January 24, 2017. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the ‘284 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the ‘284 patent is attached as Exhibit B.

39. Pursuant to the Federal Food, Drug, and Cosmetic Act (“FFD&C Act”), 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Taiho has submitted information concerning the ‘284 patent to the FDA in connection with NDA No. 207981, identifying it as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” The ‘284 patent has been listed in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”) as covering Lonsurf®.

40. Claim 1 of the ‘284 patent is directed, *inter alia*, to a method for treating at least one of a digestive cancer and a breast cancer, comprising (i) orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ration of 1:0.5 at a dose of 50 to 70 mg/m<sup>2</sup>/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, (ii) wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m<sup>2</sup> is the human patient’s body surface area.

41. Claim 18 of the ‘284 patent is directed, *inter alia*, to a method for treating colorectal cancer comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD)

and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m<sup>2</sup>/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m<sup>2</sup> is the human patient's body surface area

42. The approved Lonsurf® product labeling instructs medical personnel and/or patients to perform the steps of at least one claim of the '284 patent.

43. The use of Lonsurf® by patients and/or medical personnel in accordance with its approved product labeling by medical personnel and/or patients necessarily results in the performance of each step of at least one claim of the '284 patent.

44. The '833 patent, entitled "Stable Crystal Form of Tipiracil Hydrochloride and Crystallization Method for the Same," was duly and legally issued by the USPTO on December 27, 2016. A reexamination certificate issued for the '833 patent on September 16, 2019. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the '833 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '833 patent is attached as Exhibit C.

45. Pursuant to FFD&C Act, 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Taiho has submitted information concerning the '833 patent to the FDA in connection with NDA No. 207981, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '833 patent has been listed in the FDA's Orange Book as covering Lonsurf® and methods for using it.

46. Claim 1 of the '833 patent is directed, *inter alia*, to a crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H-3H)-pyrimidinedione hydrochloride, which is crystal Form I,

exhibiting peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.1^\circ$ ) in powder X-ray diffraction.

47. The Lonsurf® product and its approved labeling describe a product that embodies at least one claim of the ‘833 patent.

48. The ‘666 patent, entitled “Stable Crystal Form of Tipiracil Hydrochloride and Crystallization Method for the Same,” was duly and legally issued by the USPTO on October 29, 2019. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the ‘666 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the ‘666 patent is attached as Exhibit D.

49. Pursuant to FFD&C Act, 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Taiho has submitted information concerning the ‘666 patent to the FDA in connection with NDA No. 207981, identifying it as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” The ‘666 patent has been listed in the Orange Book as covering Lonsurf®.

50. Claim 1 of the ‘666 patent is directed, *inter alia*, to a crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H-3H)-pyrimidinedione hydrochloride exhibiting powder X-ray peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.2^\circ$ ), and having a purity of at least 90% by mass.

51. The Lonsurf® product and its approved labeling describe a product that embodies at least one claim of the ‘666 patent.

**NATCO'S ANDA PRODUCT**

52. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. § 355(j), Natco submitted ANDA No. 214008 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco's ANDA Product within the United States prior to the expiration of the patents-in-suit.

53. Upon information and belief, Natco's ANDA No. 214008 identified Taiho's Lonsurf® (trifluridine and tipiracil) tablets and included a written certification, as required by FFD&C Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the '284 and '833 patents are invalid or otherwise will not be infringed by Natco's ANDA Product.

54. On or about November 21, 2019, Taiho received a letter from Natco purporting to be a written notice that Natco had filed ANDA No. 214008 seeking approval to market Natco's ANDA Product prior to the expiration of the '284 and '833 patents, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV notice letter"). The Paragraph IV notice letter included notice of Natco's allegations that the '284 and '833 patents are invalid and/or not infringed by Natco's ANDA Product.

55. Natco's submission of ANDA No. 214008, including the Paragraph IV certification, to the FDA constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2).

56. Natco's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product upon approval of ANDA No. 214008 and before expiration of the patents-in-suit will infringe at least claims 1 and 18 of the '284 patent, at least claim 1 of the '833 patent, and at least claim 1 of the '666 patent under 35 U.S.C. § 271(a), (b), and/or (c).

57. Taiho commenced this action within 45 days of receiving Natco's Paragraph IV notice letter.

**COUNT I – INFRINGEMENT OF U.S. PATENT NO. RE46,284 E**

58. Paragraphs 1-57 are incorporated by reference as though fully set forth herein.

59. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets according to the Lonsurf® product labeling satisfies at least claims 1 and 18 of the '284 patent.

60. Upon information and belief, Natco's ANDA Product has the same use as Lonsurf®, at least because Natco's ANDA No. 214008 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

61. Upon information and belief, the proposed product labeling for Natco's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

62. Upon information and belief, Natco's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

63. Upon information and belief, Natco's ANDA Product, or the use or manufacture thereof, is covered by at least claims 1 and 18 of the '284 patent.

64. Natco's submission of ANDA No. 214008 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Natco's ANDA Product prior to the expiration of the '284 patent constitutes infringement of at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(e)(2).

65. Claim 1 of the '284 patent recites "A method for treating at least one of a digestive cancer and a breast cancer, comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m<sup>2</sup>/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer,

wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein  $m^2$  is the human patient's body surface area."

66. Discovery will likely show that the product labeling for Natco's ANDA Product will instruct medical personnel and/or patients to treat a digestive cancer by orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/ $m^2$ /day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of a digestive cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein  $m^2$  is the human patient's body surface area. Discovery will also likely show that the proposed product labeling for Natco's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

67. Claim 18 of the '284 patent recites "A method for treating colorectal cancer in a human patient, comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/ $m^2$ /day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein  $m^2$  is the human patient's body surface area."

68. Discovery will likely show that the product labeling for Natco's ANDA Product will instruct medical personnel and/or patients to treat colorectal cancer in a human patient, comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-

chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m<sup>2</sup>/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m<sup>2</sup> is the human patient's body surface area. Discovery will also likely show that the proposed product labeling for Natco's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

69. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Natco's ANDA Product in the United States.

70. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '284 patent, with knowledge of said patent and said infringement.

71. Upon information and belief, the proposed product labeling for Natco's ANDA will instruct medical personnel and/or patients to perform the steps of at least claims 1 and 18 of the '284 patent.

72. Upon information and belief, the use of Natco's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claims 1 and 18 of the '284 patent.

73. Upon information and belief, Natco specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Natco knows infringe at least claims 1 and 18 of the '284 patent.

74. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(c) by selling or offering to sell Natco's ANDA Product in the United States, with knowledge of the '284 patent and that there is no substantial non-infringing use of Natco's ANDA Product.

75. Upon information and belief, Natco knows that Natco's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claims 1 and 18 of the '284 patent.

76. Natco's ANDA Product constitutes a material part of the invention covered by at least claims 1 and 18 of the '284 patent.

77. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 214008 shall be no earlier than the date on which the '284 patent expires, including any patent term and regulatory extensions.

78. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Natco's infringement of the '284 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

79. Upon information and belief, Natco was aware of the '284 patent prior to Natco submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without reasonable basis for a good faith belief that it would not be liable for infringing the '284 patent.

**COUNT II – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT  
NO. RE46,284 E**

80. Paragraphs 1-79 are incorporated by reference as though fully set forth herein.

81. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets according to the Lonsurf® product labeling satisfies at least claims 1 and 18 of the '284 patent.

82. Upon information and belief, Natco's ANDA Product has the same use as Lonsurf®, at least because Natco's ANDA No. 214008 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

83. Upon information and belief, the proposed product labeling for Natco's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

84. Upon information and belief, Natco's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

85. Upon information and belief, Natco's ANDA Product, or the use or manufacture thereof, is covered by at least claims 1 and 18 of the '284 patent.

86. Natco's submission of ANDA No. 214008 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Natco's ANDA Product prior to the expiration of the '284 patent constitutes infringement of at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(e)(2).

87. Claim 1 of the '284 patent recites "A method for treating at least one of a digestive cancer and a breast cancer, comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m<sup>2</sup>/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days

followed by 2 days off treatment in the week on a one-week dosing schedule wherein  $m^2$  is the human patient's body surface area."

88. Discovery will likely show that the product labeling for Natco's ANDA Product will instruct medical personnel and/or patients to treat a digestive cancer by orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/ $m^2$ /day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of a digestive cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein  $m^2$  is the human patient's body surface area. Discovery will also likely show that the proposed product labeling for Natco's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

89. Claim 18 of the '284 patent recites "A method for treating colorectal cancer in a human patient, comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/ $m^2$ /day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein  $m^2$  is the human patient's body surface area."

90. Discovery will likely show that the product labeling for Natco's ANDA Product will instruct medical personnel and/or patients to treat colorectal cancer in a human patient, comprising orally administering a composition comprising  $\alpha,\alpha,\alpha$ -trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of

70 mg/m<sup>2</sup>/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m<sup>2</sup> is the human patient's body surface area. Discovery will also likely show that the proposed product labeling for Natco's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

91. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Natco's ANDA Product in the United States.

92. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '284 patent, with knowledge of said patent and said infringement.

93. Upon information and belief, the proposed product labeling for Natco's ANDA will instruct medical personnel and/or patients to perform the steps of at least claims 1 and 18 of the '284 patent.

94. Upon information and belief, the use of Natco's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claims 1 and 18 of the '284 patent.

95. Upon information and belief, Natco specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Natco knows infringe at least claims 1 and 18 of the '284 patent.

96. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(c) by selling

or offering to sell Natco's ANDA Product in the United States, with knowledge of the '284 patent and that there is no substantial non-infringing use of Natco's ANDA Product.

97. Upon information and belief, Natco knows that Natco's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claims 1 and 18 of the '284 patent.

98. Upon information and belief, Natco was aware of the '284 patent prior to Natco submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95.

99. Upon information and belief, Natco acted, and upon the FDA's approval of ANDA No. 214008, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '284 patent.

100. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Natco's making, using, offering to sell, selling and/or importing Natco's ANDA Product, inducement therefor or contribution thereto, will infringe the '284 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

101. Pursuant to 28 U.S.C. § 2201 and 35 U.S.C. § 271(e)(4)(A), Taiho is entitled to a declaratory judgment that the effective date of any approval of ANDA No. 214008 shall be no earlier than the date on which the '284 patent expires, including any patent term and regulatory extensions.

102. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Natco's ANDA Product with its proposed labeling, or any other Natco drug that is covered by or whose use is covered by the '284 patent, will infringe, induce the infringement

of, and contribute to the infringement by others of the '284 patent, and that the claims of the '284 patent are not invalid.

**COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,527,833 C1**

103. Paragraphs 1-102 are incorporated by reference as though fully set forth herein.

104. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '833 patent.

105. Upon information and belief, Natco's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '833 patent.

106. Natco's submission of ANDA No. 214008 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Natco's ANDA Product prior to the expiration of the '833 patent constitutes infringement of at least claim 1 of the '833 patent under 35 U.S.C. § 271(e)(2).

107. Claim 1 of the '833 patent recites "A crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride, which is crystal Form I, exhibiting peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.1^\circ$ ) in powder X-ray diffraction."

108. Natco's ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Natco's ANDA Product contains a crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride, which is crystal Form I, that exhibits peaks at two or more angles from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.1^\circ$ ) in powder X-ray diffraction.

109. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claim 1 of the '833 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Natco's ANDA Product in the United States.

110. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claim 1 of the '833 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '833 patent, with knowledge of said patent and said infringement.

111. Upon information and belief, the use of Natco's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '833 patent.

112. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claim 1 of the '833 patent under 35 U.S.C. § 271(c) by selling and offering to sell Natco's ANDA Product in the United States, with knowledge of the '833 patent and that there is no substantial non-infringing use of Natco's ANDA Product.

113. Upon information and belief, Natco knows that Natco's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '833 patent.

114. Natco's ANDA Product constitutes a material part of the invention covered by the claims of the '833 patent.

115. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 214008 shall be no earlier than the date on which the '833 patent expires, including any patent term and regulatory extensions.

116. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Natco's infringement of the '833 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

117. Upon information and belief, Natco was aware of the ‘833 patent prior to Natco submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ‘833 patent.

**COUNT IV – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT  
NO. 9,527,833 C1**

118. Paragraphs 1-117 are incorporated by reference as though fully set forth herein.

119. Taiho’s Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the ‘833 patent.

120. Upon information and belief, Natco’s ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the ‘833 patent.

121. Claim 1 of the ‘833 patent recites “A crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride, which is crystal Form I, exhibiting peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.1^\circ$ ) in powder X-ray diffraction.”

122. Natco’s ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Natco’s ANDA Product contains a crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride, which is crystal Form I, that exhibits peaks at two or more angles from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.1^\circ$ ) in powder X-ray diffraction.

123. Natco’s submission of ANDA No. 214008 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Natco’s

ANDA Product prior to the expiration of the ‘833 patent constitutes infringement of at least claim 1 of the ‘833 patent under 35 U.S.C. § 271(e)(2).

124. Upon information and belief, upon the FDA’s approval of ANDA No. 214008, Natco will infringe at least claim 1 of the ‘833 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Natco’s ANDA Product in the United States.

125. Upon information and belief, upon the FDA’s approval of ANDA No. 214008, Natco will infringe at least claim 1 of the ‘833 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the ‘833 patent, with knowledge of said patent and said infringement.

126. Upon information and belief, the use of Natco’s ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the ‘833 patent.

127. Upon information and belief, upon the FDA’s approval of ANDA No. 214008, Natco will infringe at least claim 1 of the ‘833 patent under 35 U.S.C. § 271(c) by selling and offering to sell Natco’s ANDA Product in the United States, with knowledge of the ‘833 patent and that there is no substantial non-infringing use of Natco’s ANDA Product.

128. Upon information and belief, Natco knows that Natco’s ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the ‘833 patent.

129. Upon information and belief, Natco was aware of the ‘833 patent prior to Natco submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95.

130. Upon information and belief, Natco acted, and upon the FDA's approval of ANDA No. 214008, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '833 patent.

131. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Natco's making, using, offering to sell, selling and/or importing Natco's ANDA Product, inducement therefor or contribution thereto, will infringe the '833 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

132. Pursuant to 28 U.S.C. § 2201 and 35 U.S.C. § 271(e)(4)(A), Taiho is entitled to a declaratory judgment that the effective date of any approval of ANDA No. 214008 shall be no earlier than the date on which the '833 patent expires, including any patent term and regulatory extensions.

133. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Natco's ANDA Product with its proposed labeling, or any other Natco drug that is covered by or whose use is covered by the '833 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '833 patent, and that the claims of the '833 patent are not invalid.

**COUNT V – INFRINGEMENT OF U.S. PATENT NO. 10,457,666 B2**

134. Paragraphs 1-133 are incorporated by reference as though fully set forth herein.

135. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '666 patent.

136. Upon information and belief, Natco's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '666 patent.

137. Natco's submission of ANDA No. 214008 seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Natco's ANDA Product prior to the expiration of the

‘666 patent constitutes infringement of at least claim 1 of the ‘666 patent under 35 U.S.C. § 271(e)(2).

138. Claim 1 of the ‘666 patent recites “Crystal Form I of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting powder X-ray peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $20 \pm 0.2^\circ$ ), and having a purity of at least 90% by mass.”

139. Natco’s ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Natco’s ANDA Product contains a Crystal Form I of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting powder X-ray peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $20 \pm 0.2^\circ$ ), and having a purity of at least 90% by mass.

140. Upon information and belief, upon the FDA’s approval of ANDA No. 214008, Natco will infringe at least claim 1 of the ‘666 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Natco’s ANDA Product in the United States.

141. Upon information and belief, upon FDA’s approval of ANDA No. 214008, Natco will infringe at least claim 1 of the ‘666 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the ‘666 patent, with knowledge of said patent and said infringement.

142. Upon information and belief, the use of Natco’s ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the ‘666 patent.

143. Upon information and belief, upon the FDA’s approval of ANDA No. 214008, Natco will infringe at least claim 1 of the ‘666 patent under 35 U.S.C. § 271(c) by selling and

offering to sell Natco's ANDA Product in the United States, with knowledge of the '666 patent and that there is no substantial non-infringing use of Natco's ANDA Product.

144. Upon information and belief, Natco knows that Natco's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '666 patent.

145. Natco's ANDA Product constitutes a material part of the invention covered by the claims of the '666 patent.

146. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Natco's infringement of the '666 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

**COUNT VI – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT  
NO. 10,457,666 B2**

147. Paragraphs 1-146 are incorporated by reference as though fully set forth herein.

148. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '666 patent.

149. Upon information and belief, Natco's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '666 patent.

150. Claim 1 of the '666 patent recites "Crystal Form I of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting powder X-ray peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle (20±0.2°), and having a purity of at least 90% by mass."

151. Natco's ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Natco's ANDA Product contains a Crystal Form I of 5-chloro-6-

(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting powder X-ray peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ( $2\theta \pm 0.2^\circ$ ), and having a purity of at least 90% by mass..

152. Natco's submission of ANDA No. 214008 seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Natco's ANDA Product prior to the expiration of the '666 patent constitutes infringement of at least claim 1 of the '666 patent under 35 U.S.C. § 271(e)(2).

153. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claim 1 of the '666 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Natco's ANDA Product in the United States.

154. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claim 1 of the '666 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '666 patent, with knowledge of said patent and said infringement.

155. Upon information and belief, the use of Natco's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '666 patent.

156. Upon information and belief, upon the FDA's approval of ANDA No. 214008, Natco will infringe at least claim 1 of the '666 patent under 35 U.S.C. § 271(c) by selling and offering to sell Natco's ANDA Product in the United States, with knowledge of the '666 patent and that there is no substantial non-infringing use of Natco's ANDA Product.

157. Upon information and belief, Natco knows that Natco's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '666 patent.

158. Upon information and belief, Natco acted, and upon the FDA's approval of ANDA No. 214008, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '666 patent.

159. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Natco's making, using, offering to sell, selling and/or importing Natco's ANDA Product, inducement therefor or contribution thereto, will infringe the '666 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

160. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Natco's ANDA Product with its proposed labeling, or any other Natco drug that is covered by or whose use is covered by the '666 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '666 patent, and that the claims of the '666 patent are not invalid.

### **REQUEST FOR RELIEF**

WHEREFORE, Taiho respectfully requests the following relief:

A. The entry of judgment on the Complaint in favor of Plaintiffs and against Defendants.

B. The entry of judgment that Natco has infringed the '284, '833, and '666 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214008 to the FDA;

C. The entry of judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product before the expiration of the '284, '833, and '666 patents including any patent term and regulatory extensions will constitute acts of infringement of the '284, '833, and '666 patents by Natco;

D. The issuance of an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 214008 shall be no earlier than the dates on which the '284, '833, and '666 patents expire, including any patent term and regulatory extensions;

E. The issuance of an injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, enjoining Natco, its officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the '284, '833, and '666 patents prior to the expiration of said patents including any patent term and regulatory extensions;

F. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) and/or 35 U.S.C. § 284 as appropriate;

G. A finding that this is an exceptional case under 35 U.S.C. § 285, and an award to Taiho of its reasonable attorneys' fees and costs; and

H. An award of any such other and further relief as the Court may deem just and proper.

ASHBY & GEDDES

By: /s/ Andrew C. Mayo \_\_\_\_\_

Steven J. Balick (I.D. #2114)  
Andrew C. Mayo (I.D. #5207)  
500 Delaware Avenue, 8<sup>th</sup> Floor  
P.O. Box 1150  
Wilmington, DE 19899  
(302) 654-1888  
sbalick@ashbygeddes.com  
amayo@ashbygeddes.com

*Attorneys for Plaintiffs Taiho Pharmaceutical Co.,  
Ltd. and Taiho Oncology, Inc.*

*Of Counsel:*

Michael D. Kaminski  
Liane M. Peterson  
FOLEY & LARDNER LLP  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5109  
(202) 672-5300  
mkaminski@foley.com  
lpeterson@foley.com

Dated: December 30, 2019